

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
12 October 2006 (12.10.2006)

PCT

(10) International Publication Number
WO 2006/105792 A1

(51) International Patent Classification:

A61M 5/142 (2006.01) A61M 5/145 (2006.01)

(21) International Application Number:

PCT/DK2006/000193

(22) International Filing Date: 6 April 2006 (06.04.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

PA 2005 00483	6 April 2005 (06.04.2005)	DK
PA 2005 00542	14 April 2005 (14.04.2005)	DK
PA 2005 00817	3 June 2005 (03.06.2005)	DK

(71) Applicant (for all designated States except US): M 2 MEDICAL A/S [DK/DK]; Gersonsvej 7,2., DK-2900 Hellerup (DK).

(72) Inventor; and

(75) Inventor/Applicant (for US only): MERNØE, Morten [DK/DK]; Høstvej 21, DK-2920 Charlottenlund (DK).

(74) Agent: BUDDE, SCHOU & OSTENFELD A/S; Vester Søgade 10, DK-1601 Copenhagen V (DK).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

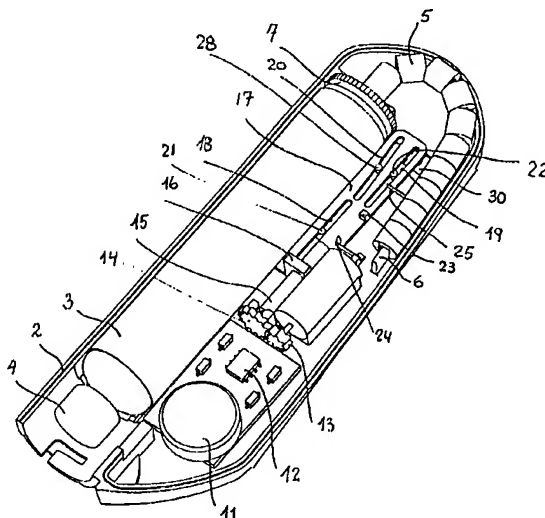
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND DEVICE FOR DISPENSING LIQUID MEDICINE BY MEANS OF A REVERSIBLE ELECTRICAL MOTOR



(57) Abstract: A method of dispensing liquid medicine comprising the steps of providing a wearable, disposable dispensing device comprising a syringe (3) having a cylinder and a plunger displaceable in the syringe cylinder for pressing medicine out of the syringe cylinder and a drive mechanism connected to the plunger for displacing the plunger in the cylinder, and an electrical motor (10) connected to a battery (11) and to the drive mechanism for providing a rotary force to the driving mechanism for displacing the plunger; displacing the plunger a certain distance in connection with a cycle of the driving mechanism comprising rotating the electrical motor in a first direction of rotation and subsequently rotating the electrical motor in the opposite direction of rotation.

METHOD AND DEVICE FOR DISPENSING LIQUID MEDICINE BY MEANS OF A REVERSIBLE ELECTRICAL MOTOR

The present invention relates to a method of dispensing liquid medicine
5 comprising the steps of providing a wearable, disposable dispensing device
comprising a syringe having a cylinder and a plunger displaceable in said
syringe cylinder for pressing medicine out of said syringe cylinder and a drive
mechanism connected to said plunger for displacing said plunger in said
cylinder, and an electrical motor connected to a battery and to said drive
10 mechanism for providing a rotary force to said driving mechanism for displacing
said plunger, displacing said plunger a certain distance in connection with a
cycle of said driving mechanism.

Methods of this type are known, wherein the electrical motor is controlled by a
15 control means so as to carry out a certain number of revolutions for each cycle
corresponding to the desired distance of displacement of the plunger.

In connection with such methods it is important that no more than the
predetermined amount of medicine be dispensed per cycle as otherwise life
20 threatening dosages may be dispensed.

When utilizing an electrical motor, a short circuit can entail that the motor does
not stop after the predetermined number of revolutions or that the motor starts
by itself.

25 Security means have been suggested to ensure that the predetermined dosage
is not exceeded, for instance monitoring the amount of liquid dispensed per
cycle or monitoring the displacement distance of the plunger or the amount of
revolutions of the motor per cycle with interruption means being activated if the
30 monitored elements exceed a certain value.

There exists a need for a simple and fail-safe method to avoid over-dosage of
medicine. One main object of the invention is to meet this need.

According to the invention this object is achieved by the cycle comprising rotating said electrical motor in a first direction of rotation and subsequently rotating said electrical motor in the opposite direction of rotation.

- 5 Hereby, any short-circuit of the motor will not entail continued rotation of the motor in one direction with ensuing continued dispensing of medicine.

The invention further more relates to a wearable, disposable medicine dispensing device comprising:

- 10 - a syringe having cylinder and a plunger displaceable in the syringe cylinder for pressing medicine out of said syringe cylinder,
- a drive mechanism connected to said plunger for displacing said plunger in said cylinder, and
- an electrical motor connected to a battery and to said drive mechanism for
15 providing a rotary force to said driving mechanism for displacing said plunger, and
- control means adapted for repeatedly reversing the direction of rotation of said electrical motor.

- 20 In the following the invention will be described more in detail in connection with two embodiments shown, solely by way of example, in the accompanying drawings, where

Fig. 1 shows a first embodiment of a device according to the invention seen in
25 perspective and with the top part of the housing removed,

Fig. 2 shows a perspective view of the drive mechanism of the device according to the invention in Fig. 1,

- 30 Fig. 3 is an exploded view of some of the drive mechanism elements of the device in Fig. 1, and

Figs. 4 and 5 are views corresponding to Fig. 2 with the drive mechanism in other positions, and

5 Figs. 6-9 are views of a second embodiment of the device according to the invention corresponding to Figs. 1, 2, 4 and 5, respectively.

Referring now to Figs. 1-5, a wearable disposable dispensing device for medicine referred to generally by the numeral 1 and of the type described in WO 2004/041330 and WO 2004/065412, the disclosure of which is hereby
10 incorporated herein by reference, comprises a housing 2, where only the bottom half is shown for the sake of clarity, a cylindrical medicine container or carpule 3 having at one end a silicone body for receiving a catheter for dispensing medicine from the interior of the carpule to a human body and being open at the opposite end to receive a flexible piston rod 5 for displacing an
15 internal not shown plunger or piston in the carpule 3 for forcing medicine out through a catheter needle assembly connected to the silicone body 4.

The flexible piston 5 is composed of segments hinged together and outwardly threaded guided by a rail 6 received in recesses in each of the segments of the
20 rod 5. The not shown outward threads (?) of the segments of the flexible piston rod 5 engage in a thread 8 of ratchet wheel 7 having teeth 9 along the periphery thereof. An electrical motor 10 electrically connected to a battery 11 and control means 12 is provided with a gear 13 meshing with a gear 14 attached to an outwardly threaded spindle or shaft 15 received in an inwardly
25 threaded nut 16 attached a plate 17 provided with two slits 18 and 19, extending parallel to the axis of said spindle 15 and a third slit 20, extending at an angle to said axis. Two fixedly arranged pins 21 and 22 are received in the slits 18 and 19, respectively such that the pins serve as guides to the to and fro displacement of the plate 17 by means of the spindle 15 when the electrical
30 motor 10 rotates first in one directional rotation and thereafter in the opposite directional rotation.

A protuberance 23 is arranged on the plate 17 to co-operate with two end stop contacts 24 and 25 electrically connected to the control means 12 for reversing the direction of rotation of the electrical motor when the protuberance 23 contacts one of the end stop contacts 24 or 25. A pawl 26 is attached to a
5 pivotable elongated body 27 having a pin 28 for being received in the oblique slit 20 and a hole 29 for receiving the pin 21 such that the body 27 is pivotable around the pin 21. A ratchet 30 is fixedly attached to the housing 2 by means of a pin 31 and is located so as to engage the teeth 9 of the ratchet wheel 7. The pawl 26 is displaceable from a retracted position where it does not engage the
10 teeth 9 of the ratchet wheel 7 and in an engaged position in which it engages the teeth of the ratchet wheel and rotates the ratchet wheel in a clockwise direction.

The displacement of the pawl 26 between the two positions indicated above
15 takes place by the linear displacement of the plate 17. When the plate 17 is displaced in the direction from the end stop contact 24 to the end stop contact 25, the oblique slit 20 urges the pin 28 of the elongated body 27 in a direction away from the carpule 3 such that the elongated body 27 pivots around the pin 21 in a clockwise direction, whereby the pawl 26 is moved in towards its
20 retracted position relative to the ratchet wheel 7. When the protuberance 23 on the plate 17 contacts the end stop contact 25, the directional rotation of the motor 10 is reversed and the plate 17 is displaced in the direction from the end stop contact 25 towards the end stop contact 24, whereby the oblique slit 20 forces the pin 28 towards the carpule 3, whereby the elongated body 27 is
25 forced to rotate in a counterclockwise direction whereby the pawl 26 is brought into contact with one of the teeth 9 of the ratchet wheel and rotates the ratchet wheel in a clockwise direction, while the ratchet rides over one of the other teeth 9 for locking the ratchet wheel against rotation in the counterclockwise direction.

30

Thus, during one circle of rotation in one direction and the opposite direction of the electrical motor 10, the ratchet wheel 7 will be advanced by one tooth

corresponding to one displacement of the pawl 26 from the retracted position thereof the engaged position thereof.

Referring now to Figs. 6-9, in this embodiment a coil spring 40 is attached to a
5 pin 41 fixedly attached to the housing 2 and a pin 42 fixedly attached to the plate 17.

When the plate 17 is moved in the direction from end contact 24 towards the end contact 25, the spring 40 is tension, and when the plate 17 moves back in
10 a direction from the end stop contact 25 towards the end stop contact 24 after reversion of the direction of rotation of the motor 10, the spring 40 will be relaxed and exert a force in the same direction as the motor 10 on the plate 17 and thus reinforcing the force available to rotate the ratchet wheel 7.

CLAIMS

1. A method of dispensing liquid medicine comprising the steps of:

- 5 - providing a wearable, disposable dispensing device comprising a syringe having a cylinder and a plunger displaceable in said syringe cylinder for pressing medicine out of said syringe cylinder and a drive mechanism connected to said plunger for displacing said plunger in said cylinder, and an electrical motor connected to a battery and to said drive mechanism for
10 providing a rotary force to said driving mechanism for displacing said plunger ,
- displacing said plunger a certain distance in connection with a cycle of said driving mechanism comprising rotating said electrical motor in a first direction of rotation and subsequently rotating said electrical motor in the
15 opposite direction of rotation.

2. A method according to claim 1 comprising the additional step of

- repeating said cycle the number of times necessary to displace said plunger
20 the distance corresponding to a required volume of medicine to be dispensed.

3. A wearable, disposable medicine dispensing device comprising:

- 25 - a syringe having cylinder and a plunger displaceable in the syringe cylinder for pressing medicine out of said syringe cylinder,
- a drive mechanism connected to said plunger for displacing said plunger in said cylinder, and
- an electrical motor connected to a battery and to said drive mechanism for providing a rotary force to said driving mechanism for displacing said
30 plunger, and
- control means adapted for repeatedly reversing the direction of rotation of said electrical motor.

4. A device according to claim 3, wherein said drive mechanism comprises
- a spindle or outwardly threaded shaft arranged for rotation by said electrical motor,
 - a displaceable body connected to said shaft and arranged for being
5 displaced by rotation of said shaft between a first position and a second position,
 - a ratchet wheel adapted for displacing a piston rod for displacing said plunger, and
 - a pawl adapted and arranged for engaging teeth of said ratchet wheel and
10 for being displaced by movement of said displaceable body between a teeth engaging position and a retracted position,
said control means comprising
 - end stop electrical contacts placed adjacent said first and second position of said body and in the path of said body during displacement of said
15 displaceable body by said shaft, and
 - electrical switch means for reversing the direction of rotation of said motor, said switch means being electrically connected to said end stop contacts such that contact of any of said end contact means caused by said displacement of said displaceable body reverses the direction of rotation of
20 said motor.

5. A device according to claim 4, wherein said pawl is arranged on or integral with a pivotable body arranged pivotable around a pivot spaced from said pawl, said pivotable body connected to said displaceable body such that
25 displacement of said displaceable body pivots said pivotable body to and fro between a third position and a fourth position corresponding to said first and second positions, respectively.

6. A device according to claim 4 or 5, wherein a spring element is attached to
30 said displaceable body such that displacement of said displaceable body to and for between said first and second positions alternatively tensions and relaxes said spring element.

7. A device according to claim 4 or 5, wherein a spring element is attached to said pivotable body such that pivoting of said pivotable body to and fro between said third and fourth positions alternatively tensions and relaxes said spring element.

5

8. A device according to any of the claims 4-7, wherein said displaceable body comprises a portion engaging the thread of said spindle such that rotation of said spindle by said electrical motor causes substantially linear displacement of said displaceable body in a first direction, and said pivotable body having a
10 linear surface portion engaging a surface portion of said displaceable body extending at an angle to said first direction.

9. A device according to any of the claims 4-8, wherein said spring element is attached to said displaceable body or to said pivotable body such that
15 displacement of said pawl from said teeth engaging position to said retracted position corresponds to tensioning of said spring element.

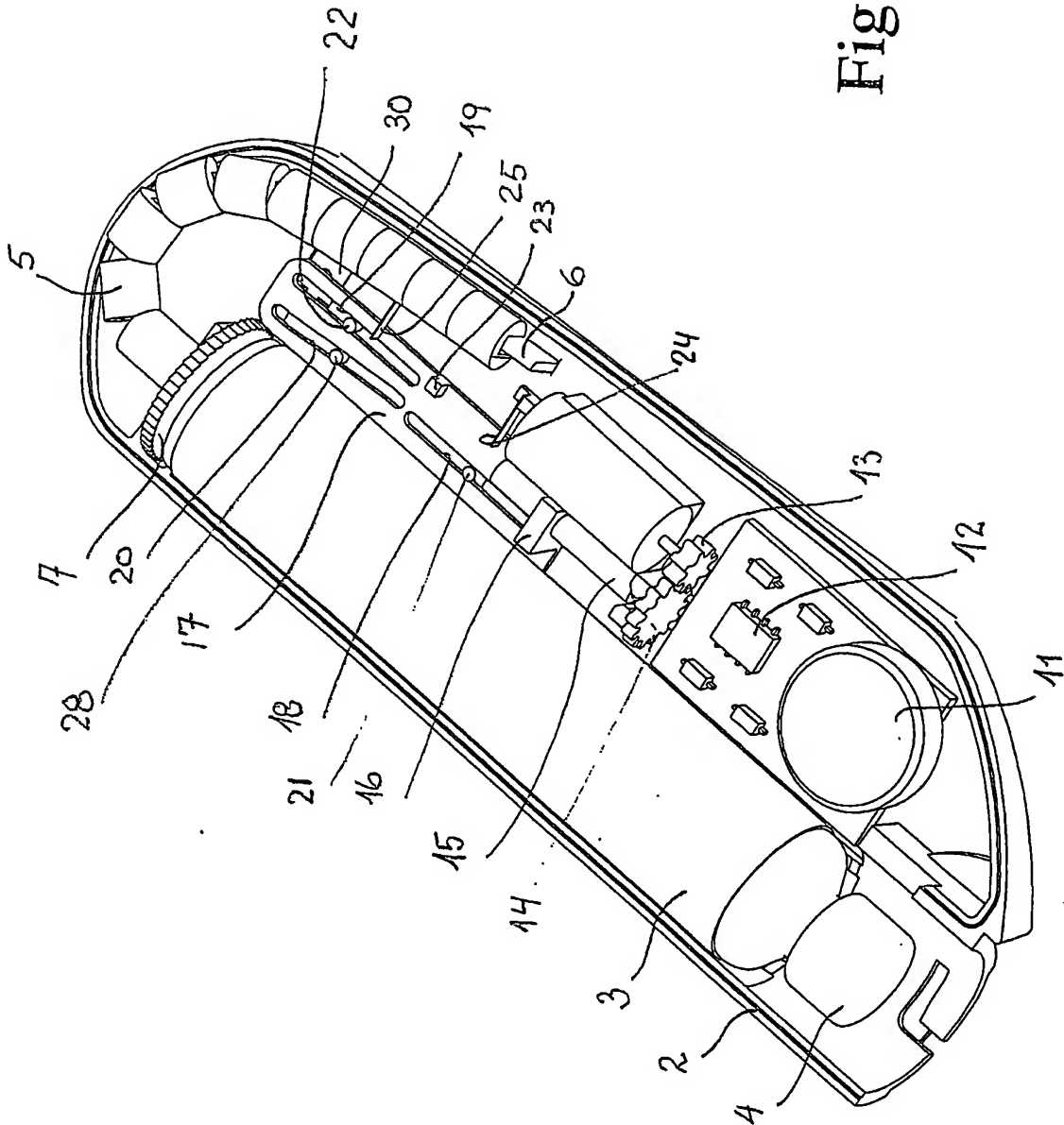


Fig. 1

2/9

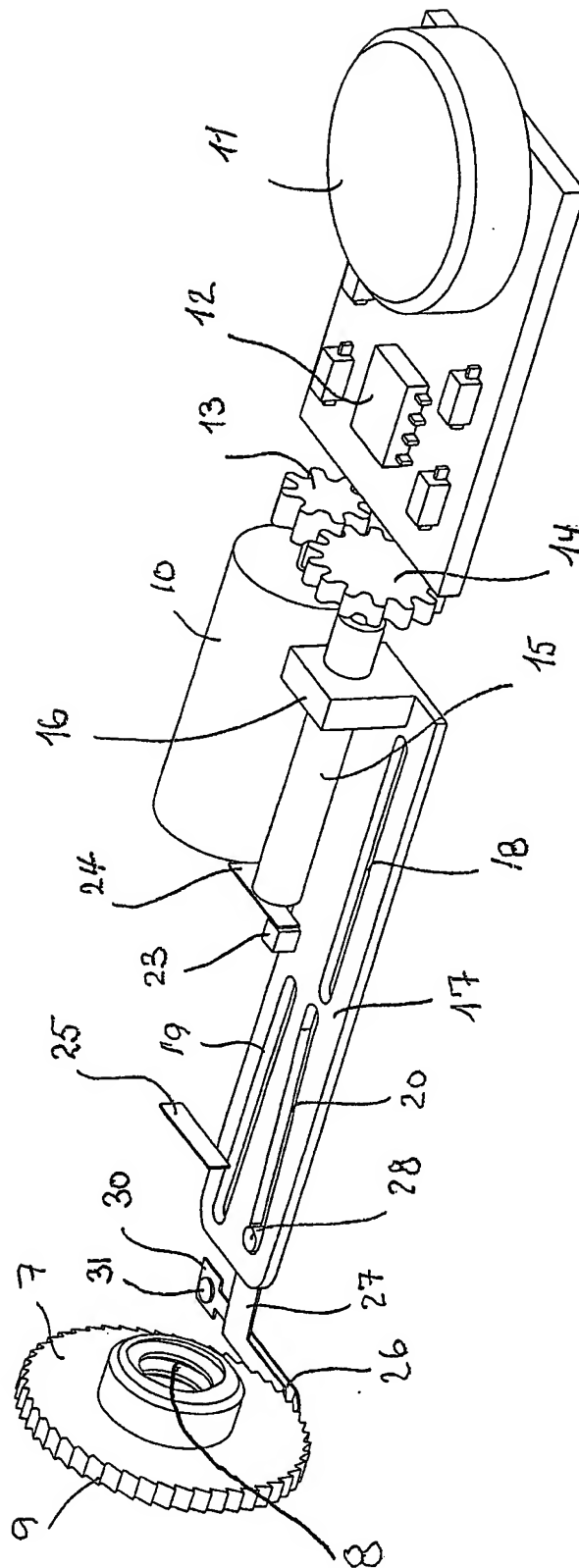


Fig. 2

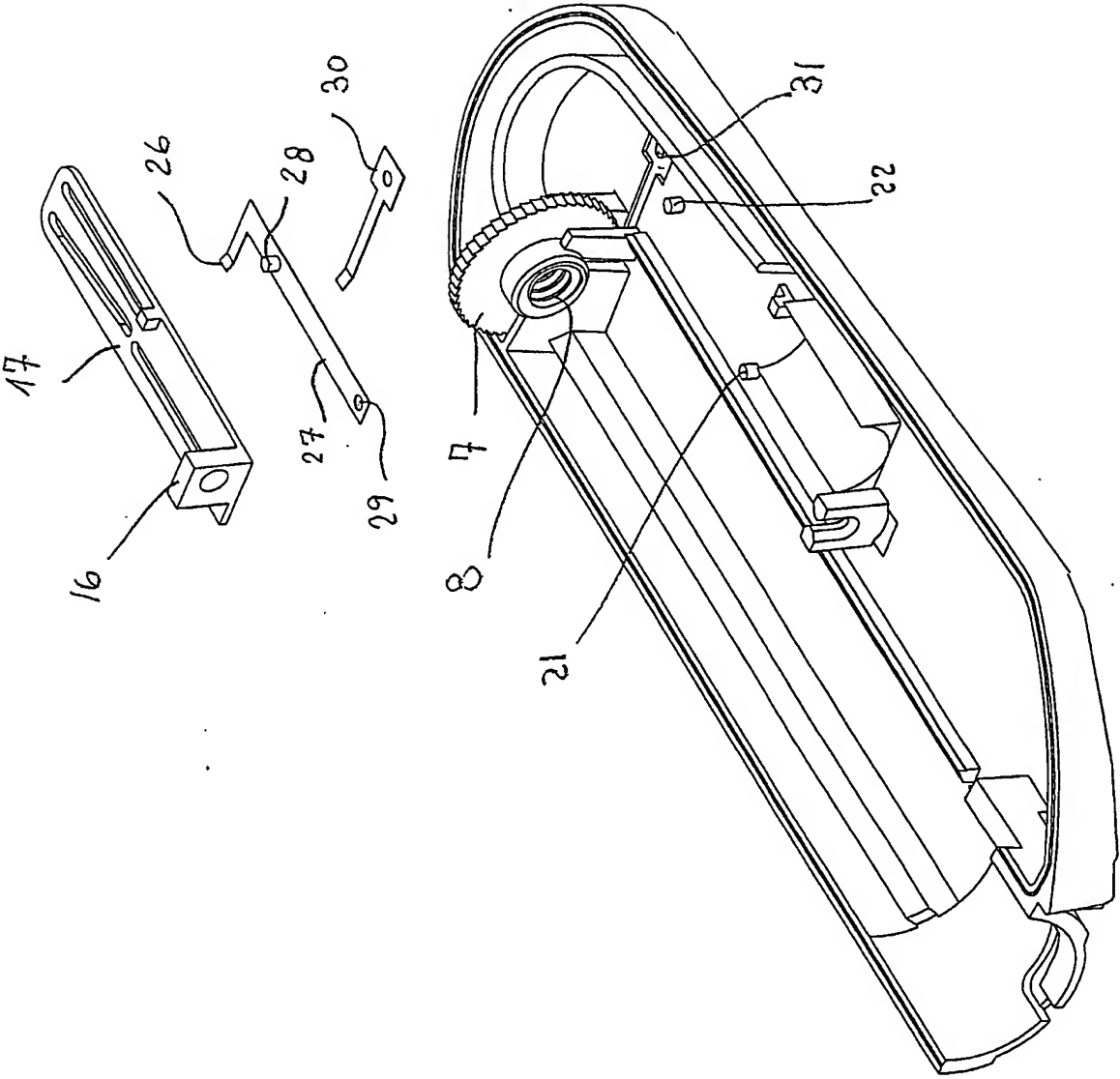


Fig. 3

4/9

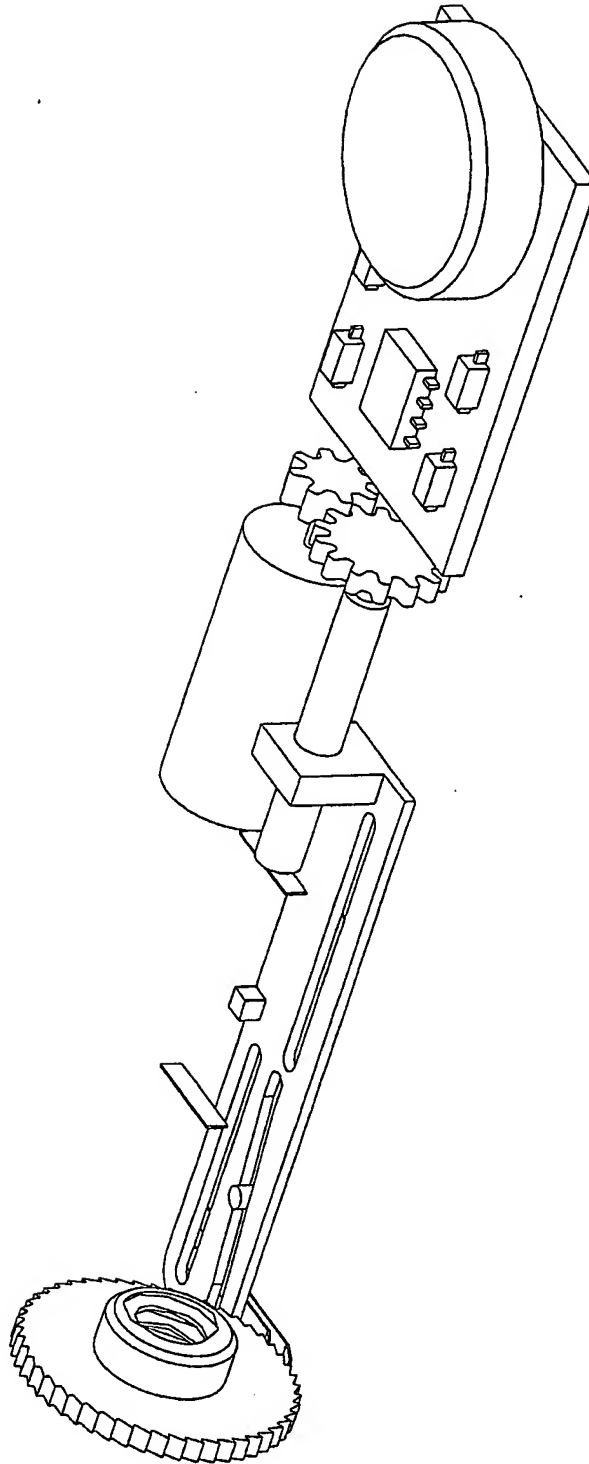


Fig. 4

5/9

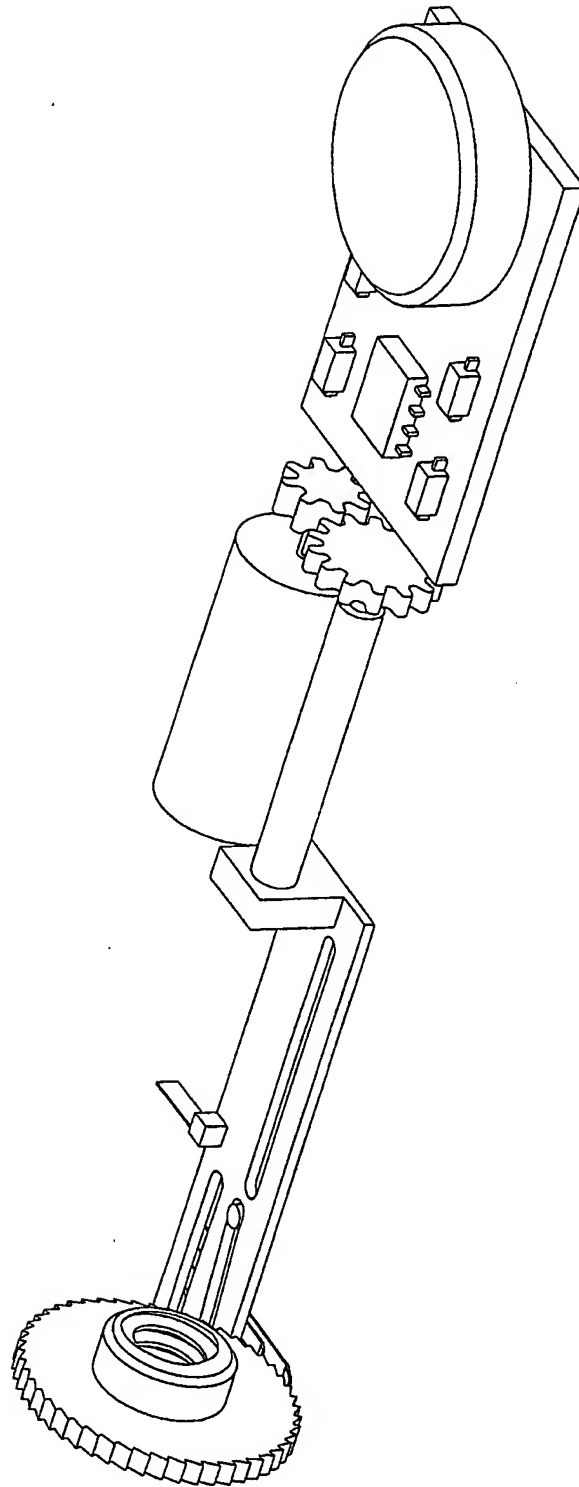
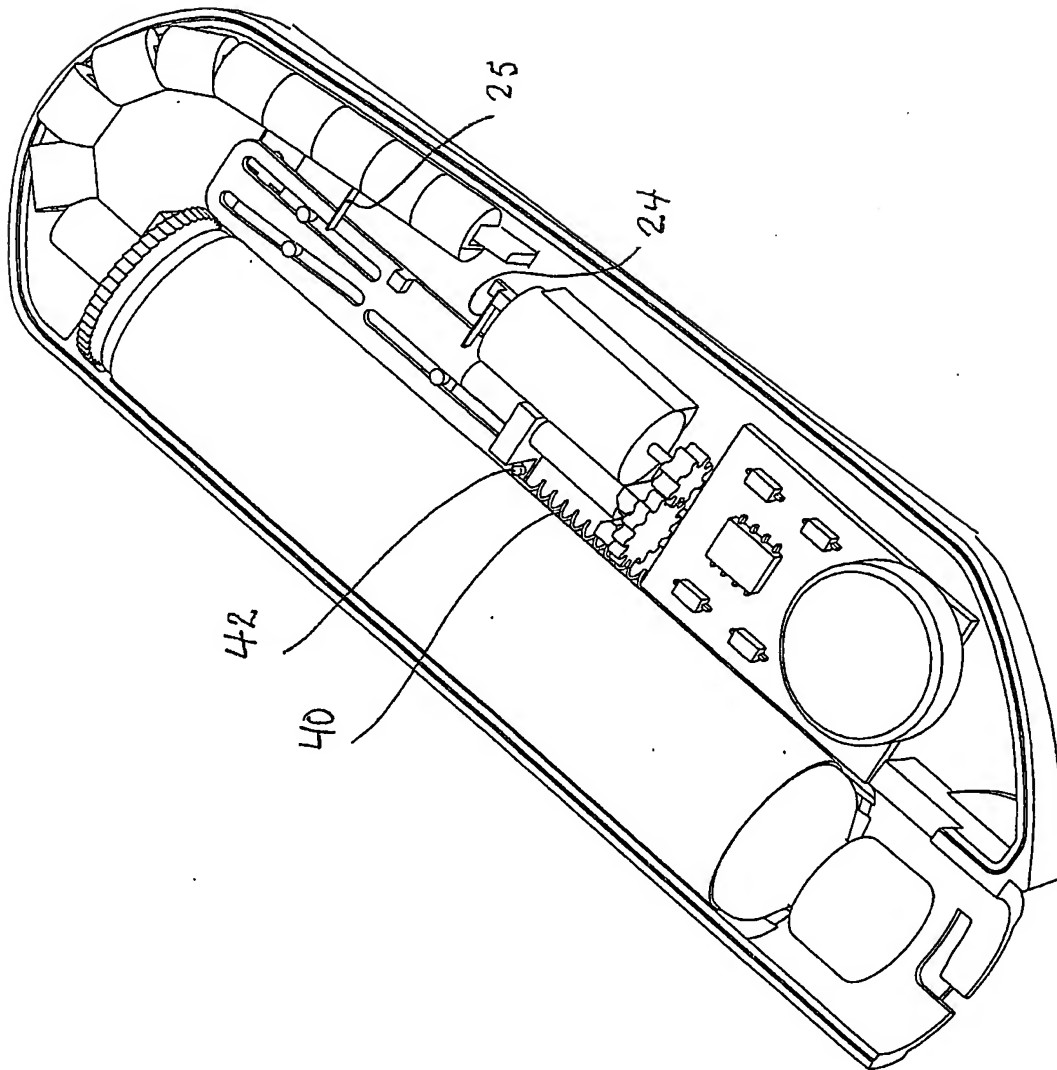


Fig. 5

Fig. 6



7/9

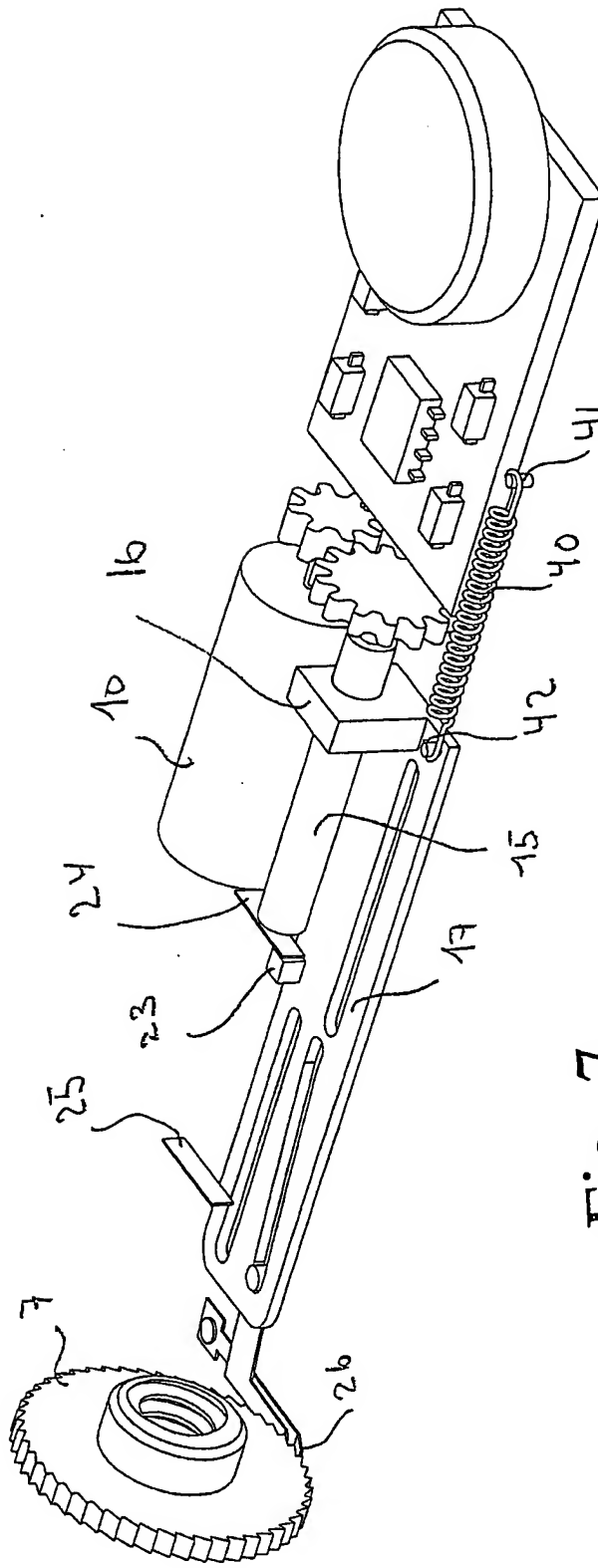


Fig. 7

8/9

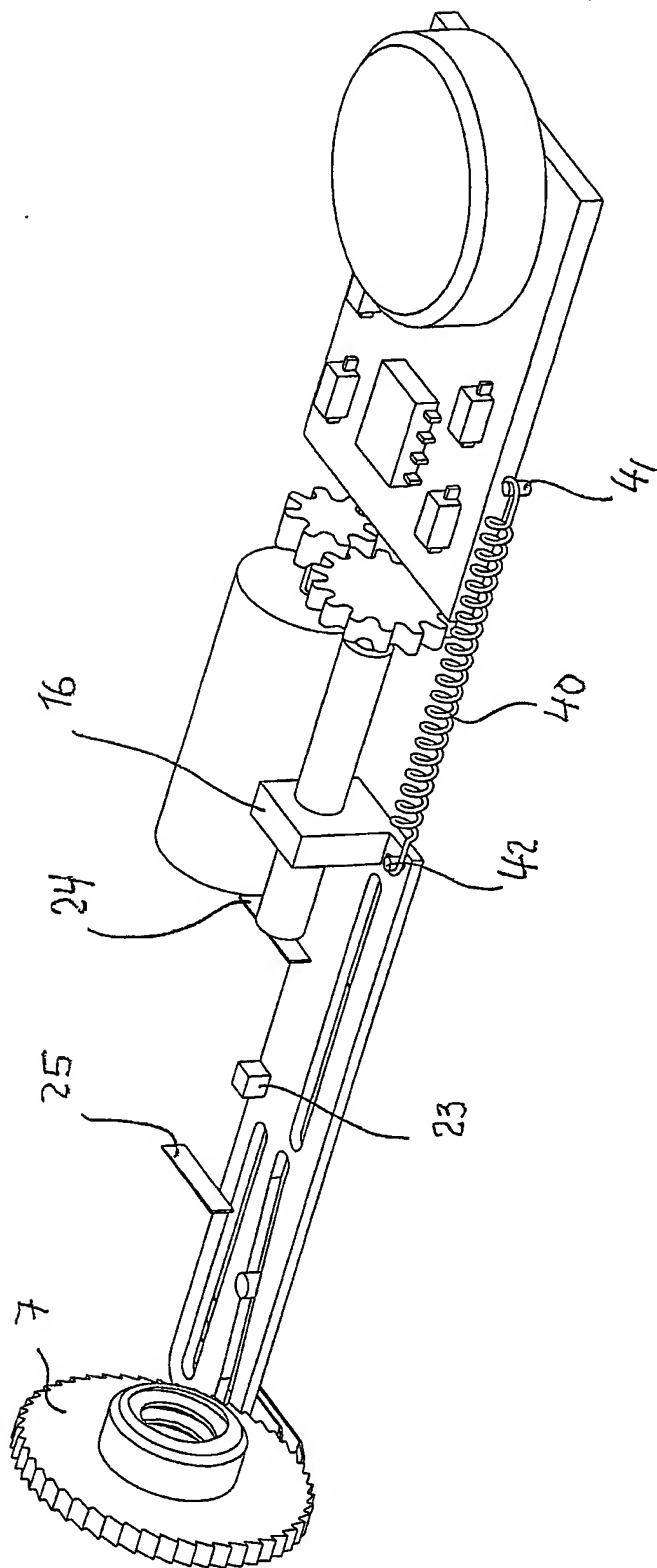


Fig. 8

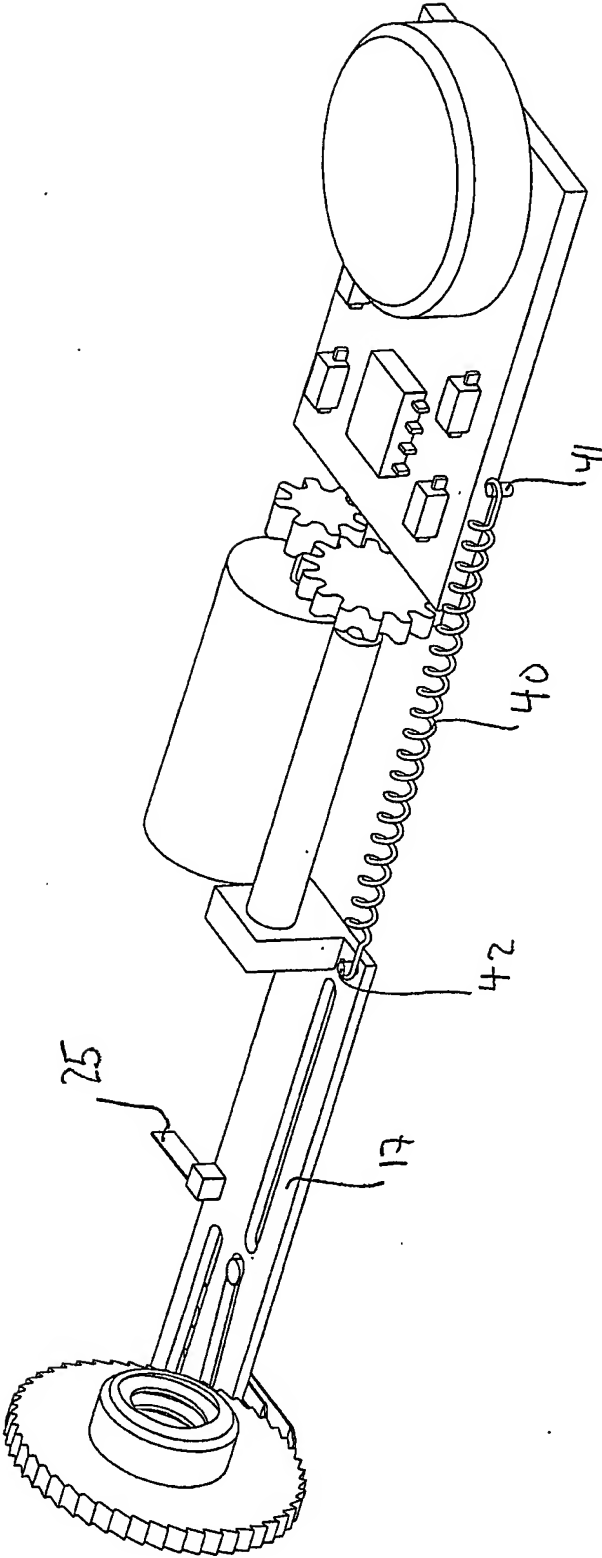


Fig. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/DK2006/000193

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/142 A61M5/145

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 2005/072794 A (M 2 MEDICAL A/S; MERNOEE, MORTEN) 11 August 2005 (2005-08-11) abstract; figures	3-9
X	PATENT ABSTRACTS OF JAPAN vol. 1999, no. 04, 30 April 1999 (1999-04-30) & JP 11 010036 A (TORAY IND INC), 19 January 1999 (1999-01-19)	3-5
Y	abstract; figures	4-9
Y	WO 2004/056412 A (M2 MEDICAL A/S; MERNOEE, MORTEN; LYNGSIE, MICHAEL, GORM) 8 July 2004 (2004-07-08) abstract; figures	4-9
	----- -/--	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

20 July 2006

Date of mailing of the international search report

02/08/2006

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Ehrsam, F

INTERNATIONAL SEARCH REPORT

International application No

PCT/DK2006/000193

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 585 252 A (GAZUIT STE NLE ELECTRONIQUE) 30 January 1987 (1987-01-30) abstract; figures -----	3,4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK2006/000193

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1, 2
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/DK2006/000193

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2005072794	A	11-08-2005	NONE	
JP 11010036	A	19-01-1999	NONE	
WO 2004056412	A	08-07-2004	AU 2003287926 A1 CN 1738656 A EP 1583571 A2 JP 2006511263 T US 2005273059 A1	14-07-2004 22-02-2006 12-10-2005 06-04-2006 08-12-2005
FR 2585252	A	30-01-1987	NONE	